



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/025,423      | 12/18/2001  | Ronald N. Zuckermann | 16141.003           | 6469             |

7590

03/26/2003

Attn: David P. Lentini  
Chiron Corporation  
P. O. Box 8097  
Emeryville, CA 94608

EXAMINER

WESSENDORF, TERESA D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/025,423

Applicant(s)

ZUCKERMANN ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 21-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1639

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group II, claims 13-29, species of formula ID and a non-duplicated array in Paper No. 10 is acknowledged.

Applicant's election with traverse of the species of a non-duplicate array is acknowledged. The traversal is on the ground(s) that the duplicate array of claim 18 cannot reasonably be considered a separate species of the claimed invention. The claimed invention is directed to a method of screening. There is no claim directed to such screening of the duplicate array (dependent claim 19 recites the use of the duplicate array for identification purposes). This is not found persuasive because the duplicate array, as admitted, is for identification purposes. Thus, a process that requires a duplicate array requires an additional step.

Claims 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Art Unit: 1639

### ***Status of Claims***

Claims 1-12 and 30-32 have been cancelled in the present amendment (2/14/03).

Claims 18-20 are withdrawn from consideration, as stated above.

Claims 13-17 and 21-29 are under examination.

### ***Specification***

The incorporation of essential material in the specification, e.g., page 10, lines 20-29 by reference to a foreign application or patent (e.g., W0 98/06437), or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Applicants are requested to further check for other incorporated publications and foreign patents since they are too numerous to mention specifically.

Art Unit: 1639

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 23, "non-selected cell type is an epithelial cell".

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-17 and 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 13 is confusing. The preamble recites for screening. The body of the claim recites for identifying. Identifying entails a different process steps.

Art Unit: 1639

B. Claim 16 incorrectly depends on claim 15. There is no antecedent basis of support for "the step of releasing the peptoides from the particles..." (This claim should depend on claim 14, which contains this limitation). Furthermore, claim 16 is confusing when performed prior to the first step(i). The preamble does not recite a solid particle bound peptides. This rejection has similar import to claim 17.

C. Claim 21 is indefinite as to the characterization of the identifying step by reciting its effect, rather than any identifying step. "Capable of selectively delivering" fails to uncertain the claimed invention with precision. Further, it is not clear as to the basis of a "selected cell type". This claim broadens the base claim.

D. The proviso in claim 24 of "at least one group Rb is not hydrogen". Since there is only one Rb hence, it is not clear as to this negative limitation.

E. Claim 28 is confusing as to the recited "at least one Rb group". There is only one Rb in the formula I. This claim broadens the base claim 24. The base claim does not recite a cationic or uncharged group. The specification recites this limitation as another embodiment of the invention. This rejection also applies to claim 29.

**Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-17 and 21-22, 24-25 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Murphy et al (PNAS, 2/98).

Murphy et al discloses at page 1517, col. 1 and col. 2 and page 1518, RESULTS section heading up to page 1522, a method of identifying transfection peptoids comprising screening a diverse library of cationic N-substituted glycine peptoids oligomer of varying chain length (library of peptoids, as claimed). The peptoids is then complexed with DNA, transfecting cells lines such as the tumor cell lines NIH3T3, HT 1080 and COS cells with the peptoid-DNA complex. The N-terminal modified peptoids (i.e., peptoid-lipid conjugate) is shown at Table 1 and 2, page 1519. Screening for those peptoids that mediated transfection of the cell lines are shown in Fig. 5, page 1521. The peptoids that transfected the cells are identified at page 1521, col. 1 and

Art Unit: 1639

col. 2. Accordingly, the method of Murphy employing specific method steps and components fully meets the broad claimed process steps and components.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-17 and 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murphy in view of Fasbender et al (US 5,935,936).

Murphy is discussed, above. Murphy does not disclose the lipid steroid, as the elected species, attached to the peptoid. However, Fasbender et al discloses at col. 4, line 11 up to col. 13, line 3; cationic amphiphiles containing steroid, as the commonly known DC-chol". These cationic amphiphiles enhance interaction of the amphiphiles with therapeutic molecules (such as nucleic acids), or with cell structures (such as plasma membrane glycoproteins), thereby contributing to successful entry of the therapeutic molecules into cells, or processing



Art Unit: 1639

within subcompartments (such as an endosome) thereof.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the lipid in the peptoid of Murphy with another lipid, as the commonly known D-chol, as taught by Fasbender. One having ordinary skill in the art would have been motivated to replace the conventional lipid as DOPE of Murphy with D-chol. The Fasbender reference provides the motivation i.e., successful entry of the DNA to cells which is five to ten times better than the conventional lipid.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

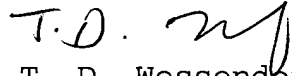
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Application/Control Number: 10/025,423

Page 9

Art Unit: 1639

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

March 21, 2003